



In the picture above, both nosepieces are held by very flexible tubing. The left side shows what happens when flimsier tubing is substituted with a regular nosepiece. It turns right over due to gravity because the tubing is so easy to twist it offers no resistance. That is why nobody has used this kind of tubing for cannulas. The idea to soften the tubing seems obvious but in practice it causes other problems that outweigh any benefit.

I put a bend in each arm of the right hand nosepiece to raise the point where the tubing attaches. Now the weight of the horizontal body will cause the nosepiece to pivot about the tubing attachment points until it is at the bottom and the prongs are at the top. Now the nosepiece does not rely on the rigidity of the tubing to maintain its upright orientation so the designer is free to use tubing that bends easily when the head is turned. As the picture shows, the change to the nosepiece is relatively minor and does not improve the cannula very much by itself but when used with flexible tubing the improvement in comfort was much more than expected. My curiosity about why this was so led me to discover the link between nosepiece center of gravity and tubing stiffness.

#### **My invention**

I am seeking a patent to protect my idea of combining very flexible tubing with a nosepiece that can remain upright without relying on the stiffness of tubing. A variety of nosepiece shapes will work in this application and it is not my intent to try to patent them all. There is at least one cannula currently sold that uses a nosepiece suited for use with flexible tubing. This would markedly improve the comfort of the cannula but the manufacturer does not know that this possibility exists. They have all learned that soft

tubing does not work for cannulas. The fact that no manufacturer has made this significant improvement is fairly proof that none of them have the information I am willing to disclose. The tubing and the correct nosepieces have been around for at least ten years, however the idea to combine the two is contrary to common wisdom and a person skilled in the arts would have no expectation of success in doing so. My invention, then, is any cannula that uses my idea to increase comfort.

I invented a new nosepiece to solve additional problems with cannulas that are not fixed by the tubing. It locates itself accurately and solidly and this gives the cannula unmatched ability to consistently keep the delivery prongs pointed down the middle and not against the walls. This continues to be a problem with current cannulas and many users suffer internal sores or a bloody nose. People report that their sores heal in two days after using my cannulas.

Although not required to make this invention work, a cannula that uses this nosepiece along with the preferred tubing has almost none of the problems associated with modern cannulas. The difference in comfort is astounding and thousands of users agree. Later I have included customer comments to illustrate this point.

The last part of my invention concerns the main supply tubing. It turns out the same wonderful material can be used to make the larger tubing that connects to an oxygen source. Its flexibility makes it behave much better than regular tubing and unexpectedly eliminated a common problem with regular tubing as I will explain later

This understanding came to me after I made the cannula and is a new and fundamental discovery. This information is not known in the industry, not seen in published literature, trade journals or books nor was it alluded to in 85 cannula patents I read.

#### **Why is my cannula so comfortable compared to regular ones?**

The combination of my nosepiece design and extreme tubing flexibility make a cannula that is vastly more comfortable than any other. Later I have included comments from users of my cannulas and some of the reasons for comfort were surprising to learn.

The tubing I use is made from ultra-high molecular weight (UHMW) PVC and this gives the tubing extreme flexibility that can't be obtained with regular PVC and it is this flexibility that makes my cannula work as well as it does. Regular PVC tubing can be made fairly soft but it still isn't very flexible and, conversely, the UHMW tubing can be just as hard as currently used tubing and still work well because of its great flexibility. A high molecular weight doesn't mean the tubing is heavier, it just means that the chains of molecules are longer. UHMW PVC can be made very soft and rubbery and was intended to be a viable replacement for expensive silicone tubing.

Ordinary PVC has "memory" that causes a lot of the problems associated with cannulas. The tubing will adopt a shape over time and is slow to relax when forced into another shape. An example is the coil shape of a packaged cannula that is slow to go away when

it is removed. It will adopt a shape on the user's head that is reluctant to change when the head is moved. Pulling the tubing tight against the skin forces the tubing to follow movements. Of course the tightness causes another set of problems. My tubing has very little memory and that, combined with rubbery qualities make it work so well. Silicone also possesses those qualities and would work well in this application. Unfortunately it is difficult to bond and is very expensive.

Compared to regular PVC, my tubing feels like silk and drapes over things nicely. You can move a section of tubing and right next to it the tubing stays put. As part of a cannula it will bend freely when a person turns their head and nothing else is disturbed. With regular tubing, such a head movement will try to bend the stiff tubing and the whole length of tube is affected, usually causing the nosepiece to move. To prevent movement the tubing must be pulled tight and this tightness causes a multitude of discomforts that are the subject of a great number of patents. I have included a number of patent drawings to show the many devices intended to address these issues. **My cannula does not need to be tight and this alone eliminates every single problem associated with tightness.** The tubing I use remains flexible in cold weather where regular PVC has been known to snap in two. Even without snapping, regular PVC is so stiff it is difficult to wear. One of the intended uses of the UHMW material was in shoe soles that must remain flexible when cold.

The nosepiece solves virtually every remaining problem. The biggest of these is the tendency for cannulas to point the oxygen against the nasal walls causing a bloody nose or sores. Another is the tendency to rock from side to side under the nose; sometimes so much that one of the prongs comes out and wastes oxygen.

The vee-shaped arms of my nosepiece fit the face and touch the skin on both sides so it has no tendency to rock from side to side. The straight central section used in all other cannulas acts like a see-saw that pivots on the bridge between the nostrils. The prongs of my nosepiece are molded at a fixed angle relative to the vee-body so when the body is nestled in place the prongs are pointed down the middle of the nostrils. In fact, it is difficult to position the nosepiece so oxygen blows against the walls. My cannula is the only medical treatment available to stop bloody noses. Currently ointments and gauze are the only other options.

My nosepiece also has prongs that are extremely flexible at the ends so they don't disturb nasal hairs. I learned that once you get below a certain thickness at the tips, the sensation of something in the nose disappears since nasal hairs aren't disturbed by the thin edge. The prongs taper to Saran Wrap-like thickness at the very tips. This turns out to be very difficult to do with the dip molding process often used to make the most comfortable cannulas. I consulted with many experts in the process and ended up developing my own tooling and method. The nosepiece also uses prongs that curve inward towards the tips. This helps avoid the inward sloping walls of the nasal passages.

A major part of the cannula is a length of tubing, somewhat larger in diameter to the nosepiece tubing that begins where the two smaller tubes are joined with a two-into-one

part called a fork connector and ends with an end connector that attaches to a source of oxygen. This bigger tubing is usually the same material as the smaller ones so it has the same stiffness problems, particularly in cold weather where the material becomes so rigid that the tubing snaps in two pieces. When this piece of tubing is made from the preferred material it drapes nicely across furniture or objects, bends in a small area without disturbing the rest and lies totally flat on the floor so you feet can't get hooked underneath and is, generally much better behaved. Many times this tubing is up to fifty feet long so a trail of tubing follows the user around. As the person walks around the tubing lifts off the floor or lays back down like a silk string and tubing just inches away doesn't move a bit. That same person using regular tubing will drag long sections of the relatively stiff tubing as they move around the house and there is a much greater chance of getting the tubing caught or dragging across something sharp or hot or can get damaged or spilled. Regular tubing never really flattens out so there are plenty of places where feet can trip on it.

One major benefit of the preferred tubing is that it does not readily twist up like a phone cord. Long sections of regular PVC tubing sometimes have one or several spots where the tubing forms into a twisted loop like the individual threads of carpet. This happens to relieve torsional stress built up as a person turns around or drags it across the floor. Besides the nuisance of having the loops under foot, they often kink at the ends where the tubing reverses direction and the oxygen is restricted or completely blocked. Tubing is often molded with ribs on the inside to keep it from flattening when someone steps on it but these ribs make the problem worse when blockage is caused by kinking instead of crushing. Once a spot in the tubing is kinked the first time it will tend to kink more easily the next time.

When all the preferred elements are combined into one cannula, nearly every major problem is either eliminated or reduced in severity. It is hard to believe it could be so much more comfortable than anything else yet it looks almost the same. This is a perfect example of something where the whole is greater than the sum of the parts. Each portion of the cannula can be used by itself and make an improved cannula but when they are all used together the benefits of one part make the next part work even better and so on. One simple example of this is that very flexible tubing does not try to bend the nosepiece when it is rolled up in a package. Normal tubing acts like a coil spring and the nosepiece has to be thick enough to avoid bending under the force. My nosepiece also has to be thick enough if it is used with regular tubing but it can be thinner and lighter than usual in combination with preferred tubing. So the nosepiece is able to be better due to the flexibility of the tubing and the tubing acts better because there is less weight hanging from it. It is difficult to convey how such relatively minor changes to a cannula could possibly make so large of an improvement so I can let users help me.

I have included several customer comments (found on my website at [www.softhose.com](http://www.softhose.com)) to give an idea of the difference between mine and regular cannulas.

I was so shocked and happy at the difference they make! I can't even begin to tell you the relief I felt, instantly! Thank you so much for making these...

The only thing that has gone right about oxygen for me, so far, had been your cannula. It is so soft, so forgiving, that I truly don't know if it's in place (took a few nighttime wakeups to determine). Each night when I put it on, I think of my mother and how much she would have liked something so tender on her fragile skin during the last years of her life.

All I can say is WOW! And of course...thank you for developing this wonderful hose! I no longer have 'face dents' or behind the ear irritation and most importantly....the nose piece is SO comfortable! The cannula is so light weight that I hardly know I have one on my face! The hose I purchased from you lays on the floor and I no longer have all that tangled mess in the house and if I happen to step outside for a moment...the hose does NOT get rock hard when it is cold. Thank you! I am off to order more!

I received your cannula and can say without qualification that it is the BEST! It is super comfortable and, most important of all, it stays put. I have been on oxygen 24/7 for 6 years and have tried them all--there's no comparison. I hope you're gearing up for mass production, because when the growing world of oxygen patients find out about it they will demand it from their oxygen providers, just as they did when Helios was invented. I hope you get your patent quick and corner the market.

I did notice that the softhose cannula has the feel of a rubber band, and as such tends to stay in my nose better than the salter labs cannulas. I have always had a problem of the cannula falling out of my nose when sleeping, and would wake up with air being blown into my eyes (or my neck). Your cannula tends to stay in my nose while sleeping. This is a MAJOR bonus!

These people are not engineers and may not know the underlying physics but they know what they feel. The comments cover the cold weather flexibility, disappearance of feeling in the nose due to the very thin tips, the face hugging shape of the nosepiece that keeps it in place, the elimination of cheek grooves and sores because of low tubing tension, the rubber-like qualities that give it such flexibility and its worth as extension tubing that lays flat and resists tangling. These few examples touch on many aspects of the invention that are detailed in the application and they also provide insight as to the real world benefits that stem from certain claimed tubing properties that were rejected in the Office Action.

#### What am I not trying to patent?

1. I am not asking to patent the idea of using softer tubing to make a cannula more comfortable. In fact, it turns out to be a bad idea and is why nobody "thought" of it before. It may explain why the idea never made it all the way to a patent
2. I did not invent the tubing I use. I am the first to use it in a cannula and am the first to discover some unforeseeable and unexpected advantages.
3. The nosepiece I invented is not the only one that works with flexible tubing. In fact, a few pages earlier, I showed a nosepiece with bent arms that is a first of its kind that has what it takes to use flexible tubing and, indeed, would be better than the best on the market. It took me all of ten minutes to conceive and make the part. A person skilled in the art could read my patent, grasp the underlying